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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,485	05/25/2001	Scott D. Feighner	20251P	8604

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,485	FEIGHNER ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 7-16* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 8-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/7/05 has been entered.

2. Applicants arguments filed 12/23/04 have been entered. Amendment to claims filed 2/7/05 has been entered. Claims 1-4 and 8 have been amended, claims 5-6 cancelled, claim 7 withdrawn, and claims 9-16 newly added. Newly added claims will be examined.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action (7/18/00, paper number 1).

5. The rejection of amended claims 1, 3 and 4 under 35 U.S.C. 102 is maintained for reasons of record. Rejection of amended claim 2 is withdrawn.

Applicants argue the McKee reference (Genomics, 46:426-434, 1997) discloses a "virtual" G protein coupled receptor (GPCR) sequence, which was predicted solely on the basis of genomic DNA sequence. Applicants traverse the allegation that the amino acid sequence provided in Figure 1 of the McKee et al. reference is characterized by a 100% query match to SEQ ID NO:3 (MTL-RIA) and SEQ ID NO:5 (MTL-RIB) . Applicant also argues a comparison of the amino acid sequence provided in Figure 1 of the McKee et al. publication reveals that the deduced GPR38 protein sequence disclosed in the reference consists of 438

amino acids. In contrast, MTL-RIA (SEQ ID NO: 3) encodes a seven transmembrane domain receptor comprising 412 amino acids and MTL-RIB (SEQ ID NO: 5) encodes a five transmembrane domain receptor comprising 363 amino acids. As disclosed in the specification (see page 5 lines 24 through 30 and Figure 6), MLT-RIA and MLT-RIB represent two alternatively spliced forms of the motilin receptor. Applicant's arguments have been fully considered and found persuasive in part. The nucleic acid inherently containing the coding region for the sequence of the polypeptide disclosed in SEQ ID NO:3 (contained in nucleic acid sequence disclosed in SEQ ID NO:1) is disclosed by McKee, see attached sequence comparison. The amino acid sequence disclosed by McKee is 100% identical to amino acids 1-412 of SEQ ID NO:3. Although, the polypeptide taught by McKee is longer than the polypeptide of SEQ ID NO:3, claims 1 and 3 contain comprising language that reads on the sequence in the prior art. Further the motilin receptor disclosed by McKee comprises the amino acid sequence encoded by the nucleotide sequence set forth in SEQ ID NO:2 (SEQ ID NO:2 is contained in SEQ ID NO:1). Although, the polypeptide taught by McKee is longer than the polypeptide of SEQ ID NO:2, claim 4 contains comprising language that reads on the sequence in the prior art.

4. The rejection of amended claim 8 under 35 U.S.C. 103 is maintained for reasons of record.

Applicants traverse the obviousness rejection on the pounds that even if a skilled artisan was motivated elucidate the ligand-binding and functional properties of the GPR38 receptor disclosed by McKee et al, there would have

been a low expectation of success. Applicants argue the argument is primarily grounded in the fact that because McKee et al. (1) did not disclose the nucleotide sequence of the genomic clone, and (2) provided incorrect amino acid sequence information for GPR38, it is unlikely that an artisan would have succeeded at producing host cells expressing functional GPR38 receptors. Applicants also argue that neither the teachings of Weinshank et al. 's disclosure relating to a method for determining whether a ligand is capable of binding to a specific GPCR, or contemporaneous knowledge at the time of Applicants' invention provides the requisite sequence information required to produce a host cell expressing a functional human GPR38 receptor. Accordingly, Applicants respectfully request reconsideration and withdrawal of this obviousness rejection. Applicant's arguments have been fully considered but are not found persuasive. Claim 8 is drawn to method for determining whether a ligand is capable of binding to a human motulin receptor comprising the amino acid sequence set forth in SEQ ID NO:3 or SEQ ID NO:5. As argued above by Examiner the amino acid sequence disclosed by McKee is 100% identical to amino acids 1-412 of SEQ ID NO:3. Although, the polypeptide taught by McKee is longer than the polypeptide of SEQ ID NO:3, claims 8 contains comprising language that reads on the sequence in the prior art. Further the motilin receptor disclosed by McKee comprises the amino acid sequence encoded by the nucleotide sequence set forth in SEQ ID NO:2 (SEQ ID NO:2 is contained in SEQ ID NO:1). Although, the polypeptide taught by McKee is longer than the polypeptide of SEQ ID NO:2, claim 4 contains comprising language that reads on the sequence in the

prior art. Therefore there would have been an expectation of success to elucidate the ligand-binding and functional properties of the GPR38 receptor disclosed by McKee et al.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action (7/26/04).

7. ***Sequence Rules Compliance***

This application fails to comply with the sequence rules, 37 CFR 1.821-1.825. Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states reference must be made to the sequence by use of the assigned identifier, the identifier being SEQ ID NO. Figures 6 and 9 contain sequences, which have not been identified by SEQ ID NO:. All sequences in the Figures must be identified by their corresponding SEQ ID NO:. Compliance with sequence rules is required.

Claim Rejections - 35 USC 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 16 recites a host cell but do not recite it is isolated. The claim as currently recited encompasses naturally occurring products. Therefore, the cell as claimed is a product that occurs in nature and does not show the hand of

man, and as such is non-statutory subject matter. It is suggested that the claim be amended to recite an isolated cell to overcome this rejection.

9. ***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 14 are indefinite because the name motilin receptor does not provide any structural limitations, and the metes and bounds of the claim cannot be determined. It is unclear what structure encompasses a motilin receptor. It is suggested, to overcome the rejection, motilin be identified by SEQ ID NO.

Claims 2 and 3 are indefinite because it is not clear what is implied by the "-" on top of the "," on line 1 of claim 1 and line 1 of claim 2. If this is a typographical error it should be corrected.

Claims 13 and 15 are indefinite for depending on an indefinite base claim.

10. ***Claim Rejections - 35 USC 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 13, 14, 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a motilin receptor polynucleotide (the polynucleotide having the nucleic acid sequence disclosed in SEQ ID NOs: 1, 2 and 4) encoding the amino acid sequence disclosed in SEQ ID NOS:3 and 5, expression vector containing said polynucleotide and host cell transfected with said vector does not reasonably provide enablement for other polynucleotides, vectors or cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification has disclosed the polynucleotide of SEQ ID NO:1, 2 and 4, encoding splice variants of a motilin receptor disclosed in SEQ ID NO:3 and 5. While the person of ordinary skill in the art would, in light of the specification be able to isolate and use the motilin receptor disclosed in SEQ ID NOs: 1-5, there is no disclosure in the specification or prior art that a other receptors or variants generally classified as motilin receptors can be isolated and used without undue experimentation. The name motilin receptor does not provide any structural limitations. It is unclear what structures encompass a motilin receptor, which would have the functionality of the polypeptide encoded by the nucleic acid of SEQ ID NOs:1, 2 and 4. The scope of the claims, which encompass other polynucleotides, apart from those disclosed in SEQ ID NO:1, 2 and 5, are not enabled by the disclosure. The disclosure does not teach how to make or

identify such variants, or to use a commensurate number of the variants , which did not share all the functional properties encompassed by the peptide of SEQ ID NOs:3 and 5 encoded by the polynucleotide of SEQ ID NOs:1, 3 or 5.. Due to the large quantity of experimentation necessary to identify the polynucleotides encompassed by the claims, the lack of direction/guidance presented in the specification regarding the production, identification, purification, isolation and characterization of said polynucleotides, the unpredictability of the effects of mutation on the structure and function of polynucleotides and their encoded proteins (since mutations of SEQ ID NOS:1-5 are also encompassed by the claims), and the breadth of the claim which fail to recite critical structural features of the invention required for activity (i.e. structure and function relationship), undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

Claim Rejection 35 USC 112, 1st paragraph (Written Description)

11. Claims 10, 13, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10, 13, 14 and 15 are directed to a motilin receptor polynucleotide, vector and cell containing said polynucleotide.

The name motilin receptor does not provide any structural limitations and the name motilin receptor does not automatically infer a functionality. It is unclear what structure is encompassed by a motilin receptor. The claims encompass receptor variants of the protein named a motilin receptor, said variants may be completely unrelated, structurally and functionally to the protein of a motilin receptor disclosed in instant application. Further the limitations, "A cDNA sequence encoding a motilin receptor isolated from a host cell transfected with the nucleic acid of SEQ NO: 1" and "A cDNA sequence encoding a motilin receptor isolated from a human thyroid library" encompass receptor variants of the protein named a motilin receptor, said variants may be completely unrelated, structurally and functionally to the protein of a motilin receptor disclosed in instant application.

The claims, as written, encompass polypeptides, which may vary substantially in length and also in amino acid/polynucleotide composition. The instant disclosure of a polynucleotide of SEQ ID NO:1, 2 and 4 encoding the polypeptide of SEQ ID NO:3 and 5 does not adequately describe the scope of the use of the claimed genus, which encompasses a substantial variety of subgenera including, variants of said polypeptides/polynucleotides, chimeric constructs, fusion constructs, which may be completely, unrelated structurally and functionally to the polypeptide/polynucleotides of SEQ ID NO:1-5 A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by amino acid sequence, falling within the scope of the genus or of a recitation of structural features

common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Instant specification fails to provide sufficient descriptive information, such as definitive structural and functional features of the claimed genus of polynucleotides. There is no description of the conserved regions, which are critical to the structure, and function of the genus claimed. For example, what regions of a motilin receptor contain a definitive structural feature required for protein function? The specification proposes to discover other members of the genus by using screening assays and techniques involving probes, primers, and hybridization. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the proteins encompassed. No identifying characteristic or property of the instant polynucleotides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific a polypeptide, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species

to describe, enable and use the genus as broadly claimed. The skilled artisan cannot envision the detailed chemical structure of the encompassed proteins and, therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. It is acknowledged that the skill of the artisan in the molecular biology art is high. However, in the current instance, **there is no clear evidence of the critical special technical feature of the polynucleotides or how the critical special technical feature encompassed by the genus claimed relates to function.** Because of the lack of guidance in the prior art and current application, one skilled in the art could not predict if the variants have the same activity as the protein disclosed in SEQ ID NO:3 and 5. The receptor protein may bind motilin but have a completely different function to that of the protein disclosed by SEQ ID NO:2 and 4. Further the claims do not recite an activity for the claimed motilin receptor.

The skilled artisan cannot envision the detailed chemical structure of the encompassed compounds and, therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that,

as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid or polypeptide is itself is required. See *Fibers v. Revel*, 25 USPQ d. 1601 at 1606 (CAFC 1993) and *Amen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or

plan for obtaining the claimed chemical invention". Therefore the specification fails to disclose the activity of the claimed genus of polypeptides/polynucleotides, the critical special technical feature of the polypeptides/polynucleotides or how the critical special technical feature encompassed by the fragments and variants of claimed motilin receptor to function.

Further method of using claimed motilin receptor is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

12. The rejection under 35 U.S.C. 102 is recast in view of the amended claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, 4, 9, 10, 11, 12, 13, 14, 15, 16 are rejected under 35 U.S.C. 102(a) as being anticipated by McKee et. al. (See IDS Genomics, Viol. 46, 426-434, 1997).

McKee discloses GPR38 receptor polynucleotide/polypeptide (inherently a motilin receptor), which has 100% query match to the coding region of SEQ ID

NO:1 and comprises SEQ ID NO:2 (encodes the polypeptide comprising SEQ ID NO:3) of instant application. McKee further discloses vector containing said polynucleotide and cell containing said vector (see Materials and Methods), thereby meeting the limitation of claims 1, 3, 4, 9, 10, 11, 12, 13, 14, 15, 16 absent evidence to the contrary. Further the GPR38 is contained in a full-length genomic clone disclosed on page 427, column 1, second paragraph. Although the nucleic acid sequence encoding the GPR38 is not disclosed, the GPR38 clone inherently has the sequence, which encodes the claimed polypeptide. Sequence comparison of SEQ ID NO:1-3 and prior art of McKee is disclosed. Therefore the disclosure of McKee meets the limitations of claims 1, 3, 4, 9, 10, 11, 12, 13, 14, 15, 16, absent evidence to the contrary.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKee et. al. (See IDS McKee et. al., Genomics, Viol. 46, 426-434, 1997). in view of Weinshank et al (see prior rejection).

McKee discloses GPR38 receptor, which has 100% query match to polynucleotide encoding the receptor comprising SEQ ID NOS: 3 of instant application. Further the GPR38 is contained in a full-length genomic clone, disclosed on page 427, column 1, second paragraph. Although the nucleic acid sequence encoding the GPR38 is not disclosed, the GPR38 clone inherently has the sequence, which encodes the claimed polypeptide. The nucleotide sequence of the GPR38 is most closely related to the neurotensin receptor-I (NT-R1)(35% overall protein identity). McKee states, "The ligand-binding and functional properties of GPR38 and GPR39 remain to be determined (see Abstract). In addition, McKee states, "Further studies are required to identify the ligand-binding and functional properties of GPR38 and GPR39, as neither radiolabeled MK-0677 or neurotensin bound specifically to GPR38 and GPR39 when ex-pressed in mammalian cells (unpublished results)", see page 433, column 2, first paragraph. McKee does not disclose a specific method for determining whether a ligand is capable of binding to the GPR38 receptor.

Weinshank discloses a method for determining whether a ligand is capable of binding to a specific GPCR comprising:

(a) transfecting test cells with an expression vector encoding a GPCR

(b) exposing the test cells to the ligand;

(c) measuring the amount of binding of the ligand to receptor;

(d) comparing the amount if binding of the ligand to GPCR receptor in the test cells with the amount of binding of the ligand to control cells that have not been transfected with the receptor

(e) concluding that compounds that bind only bind to test cells are specific for GPCR.

See column24, line 31-column 25, line 18; columns 9-10; and 3.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use the GPR38 disclosed by McKee, in the methods disclosed by Weinshank to determine which ligands were capable of binding to the newly cloned receptor. Further, the ordinary artisan would have been motivated to use GPR38 in the methods disclosed by Weinshank because, as disclosed by McKee, the ligand-binding and functional properties of GPR38 remain to be determined. McKee specifically states, "further studies are required to identify the ligand-binding and functional properties" of the GPCR, GPC38. The ordinary artisan would have easily been able to produce the transfected cells required to do the assay because transfection of GPCRs is routine in the art, as is assaying for ligands (see art provided). Further, the ordinary artisan would have expected success at completing the assay because others have done the claimed assay. For example, McKee has done the assay, if not exactly the same, it is very similar to

that claimed in instant invention. McKee did not disclose all the assay steps, but the steps were inherently done to end up with his results. McKee tested the specific binding of radiolabeled MK-0677 and neurotensin to GPR38 expressed in mammalian cells (unpublished results)", see page 433, column 2, first paragraph.

Therefore based on the state of the art at the time of filing of instant application the ordinary artisan would have a reasonable expectation of success at assaying GPR38 for ligand binding.

14 No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on 571272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal Basi
Art Unit 1646
April 17 2005.

JANET ANDRES
PRIMARY EXAMINER